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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,688	01/27/2004	Anand Baichwal	540.91195CP5	2079

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EXAMINER
ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,688	BAICHWAL, ANAND	
	Examiner	Art Unit	
	James W. Rogers	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,14-16 and 18-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,14-16 and 18-30* is/are rejected.

7)☒ Claim(s) *29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 29 is objected to because of the following informalities: it depends upon cancelled claim 17; obviously this claim refers to claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,9,10,14-16 and 18-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al. (US 5,128,143) in view of Oshlack et al. (US 5,472,712 received benefit of priority date from US 5,273,760 12/24/1991) and in further view of Colombo (US 4,839,177).

Baichwal discloses sustained release excipient and tablet formulation comprised of xanthan gum and locust bean gum (within the ratio specified by applicants), a moisturizing agent (obviously the same as wetting agent), several inert diluents and a medicament (ratio of gelling agent and medicament are within the range specified by applicant). See col 4 lin 15-col 5 lin 15, col 8 lin 60-63. Regarding claims 7 and 14 Baichwal discloses in the background information the use of hydrophobic materials such as celluloses to control the release of the dose; the concentrations of the cellulose would fall within the range specified by applicant. See col 1 lin 37-col 3 lin 10. Besides the above the Baichwal patent also discloses the inert diluent can comprise microcrystalline cellulose, the inert diluent is within the range of the hydrophobic material percent weight claimed by applicant. See col 8 lin 21-27.

Baichwal does not list a solid support.

Oshlack discloses controlled release formulations (including tablets), which can contain medicaments (including nifedipine) coated with ethyl cellulose and the methods to coat the tablets including spray drying. See abstr, col 1 lin 63-col 2 lin 3, col 3 lin 24-34, col 3 lin 55-57 and col 14 lin 20. The limitation of applying a solid support to the tablet is met because the coating of ethyl cellulose in the Oshlack patent obviously gives support to the physical shape and hardness of the tablet, and in the method claims of 22,24 and 25 it appears the applicant is really just referring to a coating since the ethyl cellulose is applied to the surface of the tablet by methods such as spray drying. Regarding claim 3 the limitation of using polyethylene glycol as a wetting agent is met because the Oshlack patent employs polyethylene glycol in its tablet

formulations, since the two compounds are the same and are both employed in a controlled release dosage form it is obvious from the view of the examiner that they would have the same properties or effect. Regarding claims 6 and 10 which are just experimental optimizations of adding the ingredients (wetting agent and hydrophobic material) to the mixture, it would be obvious to the skilled artisan to optimize the methods of adding the ingredients to form the tablet through routine experimentation. The Oshlack patent also discloses the use of several alkali metal salts that meet the limitations in claim 15 and 16 for an ionizable gel strength enhancing agent because as the applicant states in the specification the ionizable gel strength enhancing agents are used for modifying the release rate of the gel formed from environmental fluids, the Oshlack patent uses the alkali metal salts as pore-formers, which are also release modifiers, therefore it is obvious that they serve the same function in the Oshlack patent as they do in the applicants claimed invention, besides this the alkali metal salts are the same therefore they would have the exact same properties and effect when used in a controlled-release formulation. See col 12 lin 11-24.

The Colombo patent is used primarily to show that ethyl cellulose as a support platform and the method to apply it was well known in the art at the time of the invention. Colombo discloses the support thickness within the ranges claimed by applicant; Colombo also discloses all the methods claimed by applicant to apply it unto the surface (spray drying, immersion and compression coating). See abstr and col 3 lin 13-15.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Baichwal teaches controlled release excipient and tablet formulations with all of the limitations claimed in applicants current application except for the use of a solid support and the specific wetting agent and medicament claimed while the Oshlack and Colombo patents are used to show that solid supports comprised of ethyl cellulose and the use of polyethylene glycol and nifedipine in controlled release formulations were well known in the art at the time of the invention. The motivation to combine the above documents would be a method for preparing a sustained release excipient and tablet formulation employing a solid support for the controlled release of nifedipine. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7,9,10,14-16 and 18-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,048,548 in view of Colombo (US 4,839,177). Claims 1-7,9,10,14-16 and 18-30 are generic to all that is recited in claims 1-45 of U.S. Patent No. 6,048,548. That is, claims 1-45 of U.S. Patent No. 6,048,548 falls entirely within the scope of claims 1-7,9,10,14-16 and 18-30 or in other words, claims 1-7,9,10,14-16 and 18-30 are anticipated by claims 1-45 of U.S. Patent No. 6,048,548. Specifically both claim an oral dosage form comprising a medicament (nifedipine), ionizable gel strength enhancing agent (alkaline earth metals), xanthan gum, locust bean gum, wetting agent (PEG), hydrophobic material, an inert diluent and a coating or solid support made from ethyl cellulose. Also both claim mostly the same concentrations, ratios and percentages or at least they are within the ranges specified for the above ingredients. The obviousness of applicant's claims and U.S. Patent No. 6,048,548 are especially obvious when combined with Colombo (US 4,839,177) who teaches solid supports comprised of ethyl cellulose with all of the limitations claimed for the solid support in applicant's current application.

Claims 1-7,9,10,14-16 and 18-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,709,677 B2 in view of Colombo (US 4,839,177). Claims 1-7,9,10,14-16

and 18-30 are generic to all that is recited in claims 1-45 of U.S. Patent No 6,709,677 B2. That is, claims 1-45 of U.S. Patent No. 6,709,677 B2 falls entirely within the scope of claims 1-7,9,10,14-16 and 18-30 or in other words, claims 1-7,9,10,14-16 and 18-30 are anticipated by claims 1-45 of U.S. Patent No. 6,709,677 B2. Specifically both claim an oral dosage form comprising a medicament (nifedipine), ionizable gel strength enhancing agent (alkaline earth metals), xanthan gum, locust bean gum, wetting agent (PEG), hydrophobic material, an inert diluent and a coating or solid support made from ethyl cellulose. Also both claim mostly the same concentrations, ratios and percentages or at least they are within the ranges specified for the above ingredients. The obviousness of applicant's claims and U.S. Patent No. 6,048,548 are especially obvious when combined with Colombo (US 4,839,177) who teaches solid supports comprised of ethyl cellulose with all of the limitations claimed for the solid support in applicant's current application.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER